REMARKS/ARGUMENTS

In this paper, claims 34, 39 and 45 have been amended for the purpose of clarifying the invention being claimed, to eliminate unnecessary limitations and to correct an erroneous dependency. No new matter has been added. Reconsideration of this Application and entry of this Amendment is respectfully requested.

Claim Objections

In the Office Action, claims 13 and 36 were objected to on grounds that the meaning of the phrase "in known circumferential location" is unclear. Claim 36 was also objected to on grounds that "Claim 35 34" should read "Claim 34."

By the foregoing amendment, the language of claims 13 and 36 has been clarified and the erroneous dependency in claim 36 has been repaired, thereby overcoming the stated objections.

35 U.S.C. §112 Rejections

In the Office Action, claims 34 and 35-36 were rejected under 35 U.S.C. §112, first paragraph, as lacking enablement with respect to the manner in which the imaging transducer is capable of providing an image of the target location along with an indication of the expected path on which the penetrator will advance, without the presence of an imageable marker. In response, Applicant calls the Examiner's attention to the section of the specification at pages 19-23 under the heading "B. Second Embodiment: Catheter With Fixedly Mounted Imaging Transducer Useable Without Marker Structure" wherein an example of the embodiment recited in claims 34 and 35-36 is described in detail. As explained, in this embodiment, certain element(s) (e.g., crystals) of the imaging transducer is/are positioned to image the expected penetrator path and to produce imaging signal(s) that are electronically distinguishable from the imaging signals produced by the other imaging elements. In this manner, selected element(s) of the imaging transducer produce the indication of the expected penetration path and no separate imageable path-indicating marker is required.

Independent claim 34, as now amended, specifies that the imaging transducer comprises "a plurality of imaging elements, at least one of said imaging elements being a penetraton path imaging element that is a) positioned to receive an image of the expected penetration path and b)

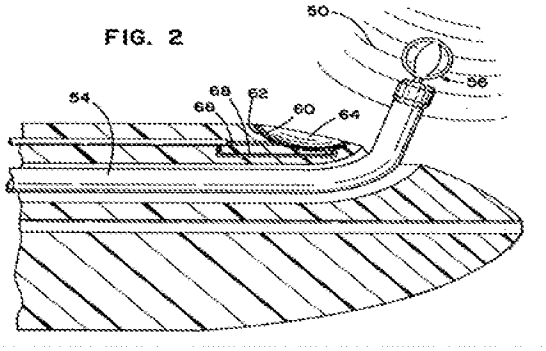
produce an image signal that is electronically distinguishable from image signals produced by the other imaging elements." Additionally, as now amended, claim 34 recites "a display that displays an image obtained from the imaging transducer, said image including the target location along with an indication of the expected penetration path which corresponds to the area imaged by said at least one penetrator path imaging element" This amended language of independent claim 34 is fully enabled by the specification (e.g., pages 19-23). Accordingly, the stated rejection under 35 U.S.C. §112, first paragraph, should be withdrawn.

35 U.S.C. §103 Rejections

In the Office Action, claims 34 and 36-45 were also rejected under 35 U.S.C. §103(a) as being obvious over United States Patent No. 5,345,940 (Seward et al.) in view of United States Patent No. 5,588,432 (Crowley).

As now amended, claim 34 recites a catheter device that is useable to direct a tissue penetrating device, substance or flow of energy from the catheter while the catheter is positioned in a vessel lumen within a patient's body to a target location outside of that vessel lumen, said catheter device comprising (a) a catheter having a proximal end and a distal end, said catheter being advanceable into the lumen of said vessel; (b) an exit location from which a tissue penetrating device, substance or flow of energy may be laterally advanced from the catheter on an expected penetration path; (c) an imaging transducer on or in the catheter, said imaging transducer comprising a plurality of imaging elements, at least one of said imaging elements being a penetraton path imaging element that is a) positioned to receive an image of the expected penetration path and b) produces an image signal that is electronically distinguishable from image signals produced by the other imaging elements; and (d) a display that displays an image obtained from the imaging transducer, said image including the target location along with an indication of the expected penetration path which corresponds to the area imaged by said at least one penetraton path imaging element, said device being thereby operative to provide, when the catheter is positioned in said vessel lumen but before advancement of the tissue penetrating device, substance or flow of energy, an image of the target location along with an indication of the expected path on which the tissue penetrating device, substance or flow of energy will subsequently advance from the catheter.

The device recited in claim 34 is quite different from anything taught or suggested by Seward et al. or Crowley. Figure 2 of Seward et al. is reproduced below for ease of reference:



Seward et al. describes a self contained ultrasound device for the delivery of therapeutic and other types of tools to be visualized in an ultrasound-type environment within the blood before, during, and after an intervention includes a catheter having a catheter body with a proximal and distal ends. The catheter contains an ultrasonic transducer (e.g., item 64) proximate its distal end. An access port is provided in the catheter for delivery of a therapeutic device (e.g., item 56) or the like to proximate the distal end of the catheter body. A guide wire port is further provided for insertion therethrough of a guide wire. Seward et al. provides no display that includes an image of a target location along with a predictive indication of the expected path on which the therapeutic device is expected to advance—before the therapeutic device has *actually* been advanced. Rather, Seward et al. ultrasonic transducer

Crowley et al. describes an acoustic imaging system for use within the heart. The described system includes a catheter, an ultrasound device incorporated into the catheter, and an electrode mounted on the catheter. The ultrasound device directs ultrasonic signals toward an internal structure in the heart to create an ultrasonic image, and the electrode is arranged for electrical contact with the internal structure. A chemical ablation device mounted on the catheter ablates at least a portion of the internal structure by delivery of fluid to the internal structure. The ablation device includes a material that vibrates in response to electrical excitation, the ablation being at least assisted by vibration of the material. The ablation device may alternatively be a transducer incorporated into the catheter, arranged to convert electrical signals into radiation and to direct the radiation toward the internal structure. The electrode may be a sonolucent structure incorporated into the catheter, through which the ultrasound device is arranged to direct signals.

An acoustic marker mounted on the catheter emits a sonic wave when electrically excited. A central processing unit creates a graphical representation of the internal structure, and super-imposes items of data onto the graphical representation at locations that represent the respective plurality of locations within the internal structure corresponding to the plurality of items of data. A display system displays the graphical representation onto which the plurality of items of data are super-imposed.

The device recited in Applicant's amended independent claim 34 is distinguishable over Seward et al. and Crowley on a number of grounds. For example, neither Seward et al. nor Crowley describe or suggest any catheter that has an imaging transducer that comprises comprising a plurality of imaging elements, at least one of said imaging elements being a penetraton path imaging element that is a) positioned to receive an image of the expected penetration path and b) produces an image signal that is electronically distinguishable from image signals produced by the other imaging elements. Nor does Seward et al. or Crowley describe or suggest any display device that displays an image obtained from an imaging transducer on a catheter along with an indication of an expected penetration path which corresponds to an area imaged by at least one penetraton path imaging element whose signal(s) is/are electronically distinguishable from the signals of the other imaging elements of the transducer. Thus, claim 34 is clearly distinguishable over Seward et al. and Crowley. Claims 36-45 depend directly or indirectly from claim 34 and are also distinguishable over Seward et al. and Crowley for at least the same reasons as claim 34 as well as other reasons not specifically articulated here.

Double Patenting Rejections

Also, in the Office Action, claims1-6, 13-14, 29-34 and 36-45 where provisionally rejected on grounds of obviousness type double patenting over claims of co pending United States Patent Applications 10/467,274 and 09/912,122, which are co-owned with the present application.

Filed herewith are terminal disclaimers to overcome the stated provisional obviousness-type double patenting rejections.

CONCLUSION

All the pending claims are now in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (707) 543-5484.

Respectfully submitted,

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